DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 22, 2014

K2M, Incorporated
Ms. Nancy Giezen
Manager, Regulatory Affairs
751 Miller Drive Southeast
Leesburg, Virginia 20175

Re: K142558
Trade/Device Name: Caspian OCT/MESA Mini/DENALI Mini Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: December 5, 2014
Received: December 8, 2014

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142558

Device Name
Caspian OCT/MESA Mini/DENALI Mini Spinal System

Indications for Use *(Describe)*

The Caspian OCT/MESA Mini/DENALI Mini Spinal System is intended to provide stabilization as an adjunct to fusion of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) when used with autograft or allograft and is indicated for the following: DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), spondylolisthesis spinal stenosis, fracture/dislocation, revision of previous cervical spine surgery, tumors, atlantoaxial fracture with instability, occipitocervical dislocation. The occipital bone screws are limited to occipital fixation only. The rod and hook components are intended for use in the cervical/upper thoracic (C1-T3) spine. The pedicle screws are limited to placement in the T1-T3 in treating thoracic conditions only. The pedicle screws are not intended to be placed in or treat conditions involving the cervical spine. The Caspian OCT/MESA Mini/ DENALI Mini Spinal System can also be linked to the RANGE® Spinal System using rod connectors or transitional rods.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Caspian OCT/MESA Mini/ DENALI Mini Spinal System

Submitter

K2M, Inc.
751 Miller Drive SE
Leesburg, VA 20175

Contact Person: Nancy Giezen
Telephone: 703-777-3155
Date Prepared: 12/19/2014

Classification

Trade Name:	Caspian OCT/MESA Mini/ DENALI Mini Spinal System
Common Name:	Spinal Fixation System
Regulatory Class:	Class II

Classification Name(s):
Spinal Interlaminal Fixation Orthosis (21 CFR 888.3050, Product Code KWP)

Predicate Device(s)

Primary Predicate
K2M Caspian OCT/MESA Mini/DENALI Mini Spinal System (K101084)
Additional Predicates
K2M Caspian OCT/MESA Mini/DENALI Mini Spinal System (K092640, K081107, K121808)
Biomet Altius (K033961)

Device Description

The Caspian OCT/MESA Mini/ DENALI Mini Spinal System is a top-loading, multiple component, posterior (occipital-cervical-thoracic) spinal fixation system. The purpose of the current submission is to add modified rods, plates and screws to the system.

Function: The system functions as an adjunct to fusion to provide immobilization of stabilization of the posterior cervical and thoracic spine.

Intended Use

The CASPIAN OCT/MESA Mini/ DENALI Mini Spinal System is intended to provide stabilization as an adjunct to function of the cervical spine and occipito-cervico-thoracic junction (occiput-T3) when used with autograft or allograft and indicated for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Spinal stenosis
- Fracture/dislocation
- Revision of previous cervical spine surgery

- Tumors
- Atlantoaxial fracture with instability
- Occipitocervical dislocation

The occipital bone screws are limited to occipital fixation only.

The rod and hook components are intended for use in the cervical/upper thoracic (C1-T3) spine. The pedicle screws are limited to placement in the T1-T3 in treating thoracic conditions only. The pedicle screws are intended to be placed in or treat conditions involving the cervical spine. The wires to be used with Caspian OCT/MESA Mini/ DENALI Mini Spinal System are intended for attachment to the posterior cervical spine.

The CASPIAN OCT/MESA Mini/ DENAIL Mini System can also be linked to the Range Spinal System using rod connectors or transitional rods.

Technological Comparison to Predicate(s)
The proposed modifications were compared to predicate systems and the design features, materials and sizes were found to be substantially the same as these systems.

Non-clinical Performance Evaluation
The worst case components of the Caspian OCT/MESA Mini/ DENALI Mini Spinal System were previously tested in accordance with ASTM F1717 and ASTM F2706 and determined to be equivalent to predicate devices. The subject implants were determined not to represent a new worst case using engineering analyses.

Conclusion
There are no significant differences between the Caspian OCT/MESA Mini/ DENALI Mini Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.